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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,463	01/10/2002	Davide R. Grasseti	107-000110US	9878
22798 7590 08/17/2009 QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C. P O BOX 458 ALAMEDA, CA 94501				
EXAMINER				
WANG, SHENGJUN				
ART UNIT		PAPER NUMBER		
1617				
MAIL DATE		DELIVERY MODE		
08/17/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/044,463

Applicant(s)

GRASSETTI ET AL.

Examiner

Shengjun Wang

Art Unit

1617

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-16 and 20-24 is/are pending in the application.
- 4a) Of the above claim(s) 3, 7-9, 13-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5, 6, 10-12 and 20-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/888)
- Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

In view of the appeal brief filed on May 4, 2009, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617

Claim Rejections 35 U.S.C. 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims are directed to a method comprising administer the disulfide compounds herein to an individual in need of immune response modulation. Examples of those individuals are given in the specification, paragraphs 0095-0102, e.g., immune compromised patients (0100), patients with Lentivirus infection (paragraph 0099) is one of the examples. The effective amounts are defined as about 10 μ g to about 5 g per kg of body weight (0087).

2. Claims 1-2, 5-6, 10-12, and 20-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Grassetti (US 4,378,364, IDS), as evidenced by Oliver, and Tagawa. .
3. Grassetti teaches a method of lessening the pains and increasing the well-being of patients with carcinomas comprising administering to the patients an effective amount of 6,6'-dithiodinicotinic acid, wherein the preferred amounts is about 500 mg to about 900 mg per day. The Patients treated in the examples include those have surgery, chemotherapy, and/or metastases, See, particularly, the examples, and the abstract and the claims. Grassetti particularly teach the administration of 6,6'-dithiodinicotinic acid at the time of surgery for cancer. Grassetti reasoning that "It is known that the manipulation of a tumor during surgery cause large number of cancer cells to enter the blood stream with concomitant high danger of formation of metastases. Treatment with the reagent should be continued for an adequate period of time both before and following surgery until the *natural defenses* of the organism have destroyed the remaining circulating cancer cells." See, column 11, lines 52 to column 12, line 8. As to "modulating an immune response," or other limitations that further define the immune response (claims 10-12), recited in the preamble, it is noted that preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a

structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

4. The added step in the claimed method: “identifying an individual in need of immune response modulation;” is inherently met by the method of treating cancer patient disclosed in the reference, as cancer patients, particularly, those who have surgery or under chemotherapy are recognized as “in need of immune response modulation” See, particularly, the abstract in Tagawa and page 198 in Oliver. Oliver specifically states: “All modalities of cancer therapy except hormone therapy (i.e., surgery, radiotherapy and chemotherapy) suppress immune responses.”

5. Further, applicant’s attention is directed to *In re Swinehart*, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated “is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art.” In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds, i.e., treating cancer patient who is in need of immune potentiation, is old and well known rendering the claimed subject matter anticipated by the prior art.

Claim Rejections 35 U.S.C. 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-2, 5-6, 10-12, and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grasseti (US 4,378,364, IDS), in view of Oliver, and Tagawa. .
8. Grasseti teaches a method of lessening the pains and increasing the well-being of patients with carcinomas comprising administering to the patients an effective amount of 6,6'-dithiodinicotinic acid, wherein the preferred amounts is about 500 mg to about 900 mg per day. The Patients treated in the examples include those have surgery, chemotherapy, and/or metastases, See, particularly, the examples, and the abstract and the claims. Grasseti particularly teach the administration of 6,6'-dithiodinicotinic acid at the time of surgery for cancer. Grasseti reasoning that "It is known that the manipulation of a tumor during surgery cause large number of cancer cells to enter the blood stream with concomitant high danger of formation of metastases. Treatment with the reagent should be continued for an adequate period of time both before and following surgery until the *natural defenses* of the organism have destroyed the remaining circulating cancer cells." See, column 11, lines 52 to column 12, line 8. As to "modulating an immune response," or other limitations that further define the immune response (claims 10-12), recited in the preamble, it is noted that preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

9. Grasseti does not teach expressly the steps for “identifying an individual in need of immune response modulation;”
10. However, Oliver specifically states: “All modalities of cancer therapy except hormone therapy (i.e., surgery, radiotherapy and chemotherapy) suppress immune responses.” See, page 198. Tagawa teaches that modulation of immune response is one of the strategies for cancer therapy. See, particularly the abstract.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to first identify a patient in need of immune modulation, such as cancer patients under surgery, or immediate before or after the cancer surgery, and/or with chemotherapy, and administer the patients a sufficient amount of 6,6'-dithiodinicotinic acid as taught by Grasseti.

A person of ordinary skill in the art would have been motivated to first identify a patient in need of immune modulation, such as cancer patients under surgery, or immediate before or after the cancer surgery, and/or with chemotherapy, and administer to the patients a sufficient amount of 6,6'-dithiodinicotinic acid as taught by Grasseti because cancer patients, particularly, those under surgery and/or chemotherapy are known to be in need of immune modulation, and 6,6'-dithiodinicotinic acid is known to lessen pain and increase well-being of cancer patients, particularly, those having surgery and/or chemotherapy. Further, 6,6'-dithiodinicotinic acid is taught to maintain or improve the natural defense (immune system) and to keep the cancer cells released during the surgery control.

Response to the Arguments

Applicants' remarks submitted in the appeal brief have been fully considered, but are moot in view of the new grounds of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shengjun Wang/
Primary Examiner, Art Unit 1617